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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,655	02/01/2002	Bruno Giannetti	054756-5003-00	1818

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EXAMINER

ROBERT, EDUARDO C

ART UNIT PAPER NUMBER

3732

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/061,655

Applicant(s)

GIANNETTI ET AL.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/18/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Priority

It is acknowledged that applicant's intention is to claim priority under 35 U.S.C. 120 of pending PCT application PCT/IB01093 as set forth in the data sheet filed on February 1, 2002 and in the remarks filed on October 6, 2004 (page 3, lines 6-13).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It appears to claim priority under 35 U.S.C. 119 and not under 120. It is noted that applicant's remarks filed on October 6, 2004 clarify that applicant is only interest on claiming priority under 35 U.S.C. 120 (see remarks filed on October 6, 2004, page 3, lines 6-13). A oath or declaration should be filed correcting the above mention contradiction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (U.S. Patent 5,769,899).

Schwartz et al. disclose an structure having a porous bio-absorbable matrix made from hyaluronic acid. It is noted that hyaluronic acid is inherently cell-free. The matrix has an overlaid of chondrocyte cells (see col. 7, lines 4-30). The cells are clearly somehow held on the matrix in order to permit vascular invasion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (U.S. Patent 5,769,899).

Schwartz et al. disclose the claimed invention except for the chondrocyte cells being autologous (claim 19), or allogenic (claim 20), or xenogenic (claim 21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the structure of Schwartz et al. with the chondrocyte cells being autologous, or allogenic, or xenogenic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed on October 6, 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that the recitation of "consisting essentially of" limits the claims to just a hyaluronic acid matrix and chondrocytes adjacent thereto, it is noted that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps **and those that do not materially affect the basic and novel characteristics of the claim invention**. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA). In the instant case the Schwartz et al. structure is not affected by the delivery unit, i.e. it does not changed the basic and novel characteristics of the structure. Furthermore, for the purposes of searching under 35 U.S.C. 102 and 103, "consisting essentially of" will be construed as equivalent to "comprising" *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355. Moreover, if applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of **showing** that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). Also, the recitation of "consisting essentially of" is not a closed claim. *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1984).

Applicant's arguments with regard to claims 19-21 do not overcome the rejections applied thereto, since applicant has not provide any convincing showing that these are nothing more than a selection of a known material on the basis of its suitability for the intended use as asserted by the examiner. Applicant has not provided any showing that such limitations are

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“critical”. In re Cole, 140 USPQ 230 (CCPA 1964); In re Kuhle, 188 USPQ 7 (CCPA 1975); In re Davies, 177 USPQ 381 (CCPA 1973). **Mere arguments by counsel cannot take the place of evidence.** In re Cole, 236 F.2d 769, 773, 140 USPQ 230, 233 (CCPA 1964); In re Walters, 168 f.2d 79, 80, 77 USPQ 609, 610 (CCPA 1948); et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

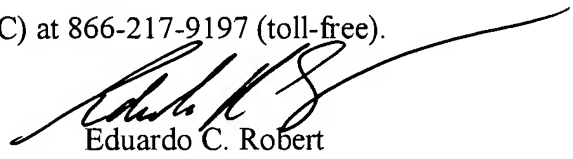
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.